

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

MDL No. 1456
Master File No. 1:01-CV-12257-PBS
Case No. 10-CV-11186-PBS

THIS DOCUMENT RELATES TO:
*United States ex rel. Ven-A-Care of the Florida
Keys, Inc.*
v.
*Baxter Healthcare Corporation and Baxter
International, Inc.*

Judge Patti B. Saris

**BAXTER HEALTHCARE CORPORATION'S OPPOSITION
TO MOTION OF LINNETTE SUN AND GREG HAMILTON
TO REOPEN THE JUDGMENT AND FOR A HEARING**

Non-parties Linnette Sun and Greg Hamilton, who are Relators in *United States ex rel. Sun and Hamilton v. Baxter*, No. 08-CV-11200 (the "Sun/Hamilton Case") but not in *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corporation and Baxter International, Inc.*, No. 10-CV-11186 (the "Ven-A-Care Case"), seek to vacate the judgment in the Ven-A-Care Case. However, Rule 60(b)(6) does not permit Sun and Hamilton to attack the settlement in the Ven-A-Care case.

First, the only relief to which Sun and Hamilton theoretically might be entitled would be a share of the settlement proceeds. They are not entitled to unravel the Ven-A-Care settlement.

Moreover, Sun and Hamilton do not have standing to bring a Rule 60(b)(6) motion in the Ven-A-Care Case because they are not "parties" or "legal representatives" of "parties" in the Ven-A-Care Case, as those terms are used in Rule 60(b).

Furthermore, Sun and Hamilton cannot make the showing that is required to vacate a judgment under Rule 60(b)(6): Sun and Hamilton's failure to timely object to the settlement cannot create the "exceptional circumstances" that would justify the "extraordinary relief" embodied in a Rule 60(b)(6) motion.

Finally, and in any event, this Court cannot grant Sun and Hamilton any relief because their *qui tam* claim – now focused solely upon the hemophilia therapy Advate¹ – is barred by the first-to-file rule.

FACTUAL BACKGROUND

On October 7, 2011, counsel for Ven-A-Care filed and served on all MDL counsel the Ven-A-Care settlement agreement. It is now undisputed that counsel for Sun and Hamilton received and read the Ven-A-Care settlement agreement, and immediately understood that it might have a bearing on the Sun/Hamilton Case. Indeed, one of Sun and Hamilton's lawyers sent an email to Ven-A-Care's lawyer, congratulating him on the settlement and asking a pointed question regarding a term defined within the body of the settlement agreement. This Court noted

¹ We hasten to remind the Court – as outlined in our October 20, 2011 partial summary judgment motion, (Dkt. 7851), that Advate was first sold in August 2003. By that time, the government was well aware of AWP pricing issues. In fact, there is no need to speculate whether the government was aware of Advate pricing because Baxter wrote letters to CMS detailing that pricing (both AWP and retail prices) as part of an effort (which found its way ultimately to federal court) to have Advate classified differently from Recombinate. *Id.* at 9-10. Thus, even if it were not the law of the case – as this Court has held – that sophisticated purchasers could not be deceived after 2000 by AWP pricing because by then "the cat was out of the bag," *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp.2d 20, 95 (D. Mass. 2007), the government had specific knowledge about J7192 reimbursement and Advate's placement within that reimbursement scheme in 2003. Finally, as we also previously demonstrated, Advate was no longer reimbursed on the basis of AWP after December 31, 2004. These facts – and the Court's prior rulings – mean that Baxter has *no* liability for Advate. On these same facts and – even *if* the Court were to change course and rule against Baxter on liability – there are zero or, at maximum, immaterial damages. And immaterial damages would not have altered the settlement negotiations or settlement amount agreed to by all parties to the Ven-A-Care final settlement. Every other Baxter AWP settlement released any and all claims regarding Advate which, of course, is the same settlement reached in Ven-A-Care (that has now twice been confirmed by this Court).

in its summary judgment decision that “it would have been quite predictable that Baxter would seek to cut off all future liability to the federal government” as part of the settlement agreement. Order at 12. In short, counsel for Sun and Hamilton had actual knowledge of the terms of the settlement, and every reason to believe it would impact Sun and Hamilton’s claims.

Despite this, Sun and Hamilton did not raise any objection with respect to the settlement prior to the Court’s approval of the settlement on October 17, 2011. Indeed, Sun and Hamilton did not alert the court to any objection until months after entry of judgment in the Ven-A-Care Case, when they raised the issue in their February 16, 2012 motion for reconsideration in the Sun/Hamilton Case.

ARGUMENT

I. ASSUMING, ARGUENDO, THAT SUN AND HAMILTON ARE ENTITLED TO BRING A MOTION UNDER RULE 60(b)(6), THEY SHOULD ONLY BE PERMITTED, AT MOST, TO CLAIM A SHARE OF THE PROCEEDS OF THE VEN-A-CARE SETTLEMENT, NOT TO ATTACK THE SETTLEMENT ITSELF

Assuming arguendo that Sun and Hamilton can bring a motion under Rule 60(b)(6) in the Ven-A-Care Case, they should be permitted, at most, to argue that they are entitled to some small share of the settlement proceeds; they should not be entitled to try to unravel the entire Ven-A-Care settlement. The Ven-A-Care settlement was the result of painstaking, good faith negotiations between Baxter and Ven-A-Care. The settlement was consented to by the Government, which has not moved to reopen the judgment. Neither Baxter nor Ven-A-Care believes that settlement to be unfair. And this Court has now twice ruled that the settlement agreement is properly interpreted to foreclose any Advate claims. It would be improper to allow Sun and Hamilton to use Rule 60(b)(6) as a device to do an end run around the Court’s

interpretation of the contract and to unravel the parties' good faith agreement resolving their dispute.

The cases cited by this Court in its opinion denying Sun and Hamilton's motion for reconsideration show that Sun and Hamilton can at most argue for a share of the proceeds of the Ven-A-Care settlement, and cannot properly seek to vacate that settlement. *United States ex rel. Bledsoe v. Community Health Systems, Inc.*, 342 F.3d 634, 648 (6th Cir. 2003), makes clear that the concern addressed by 31 U.S.C. § 3730(c)(5) is that of the government depriving a relator of her share of a settlement reached in a different action – the “alternate remedy”: “Section 3730(c)(5) seeks to insure a relator's right to a share of any proceeds obtained through an alternate remedy”² Likewise, in *United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999), a relator in one case sought intervention in another case that had been settled, but solely for the purpose of seeking a share of the settlement proceeds – not to unravel the underlying settlement.

Furthermore, in *LaCorte*, unlike here, the relator promptly objected to the settlement, seeking intervention before entry of an order of dismissal. The district court granted the motion to intervene. The Fourth Circuit reversed, holding that intervention was not authorized by the FCA. The remark relied on by Sun and Hamilton – that among the “[o]ther mechanisms” that

² *Bledsoe* also makes clear, 342 F.3d at 649-50, that Congress did not intend for the “alternate remedy” provision of 31 U.S.C. § 3730(c)(5) to be interpreted so as to increase a defendant's liability: “If indeed the government settled Relator's claims, either Defendants would assert an accord and satisfaction defense (which, if successful, would deny Relator part or all of his rightful share of the recovered funds), or Defendants would be forced to pay the civil penalties and double or treble damages associated with the very same claims for which they had already paid penalties and damages by way of the settlement. Under either result, adverse consequences (to either Relator or Defendants) would ensue that the FCA had not intended. *See* S. Rep. 99-345, at 27, 1986 U.S.C.C.A.N. at 5292 (‘While the Government will have the opportunity to elect its remedy, it will not have an opportunity for dual recovery on the same claim or claims.’); *id.* at 2, 23-24, 1986 U.S.C.C.A.N. at 5267, 5288-89 (emphasizing its intent to provide a financial incentive for relators bringing valid qui tam suits and its belief that the government and private citizens must work together to battle FCA violations).”

“are available for qui tam plaintiffs to protect their interests” is that “[i]f the relator believes that the government acted improperly in procuring a settlement, then he may return to the court which had jurisdiction over the settlement and move to reopen the judgment under Fed.R.Civ.P. 60(b)(6)” – is dicta, unnecessary to the court’s holding reversing the district court’s grant of the motion to intervene. Moreover, in *LaCorte*, unlike the present case, the relator did not sleep on his rights, but promptly objected to the settlement agreement. Because Sun and Hamilton did not raise a timely objection, they cannot make the showing of “exceptional circumstances” justifying relief under Rule 60(b)(6).

Thus, assuming that *Bledsoe* and *LaCorte* lend support to Sun and Hamilton’s Rule 60(b)(6) motion, it is support only for Sun and Hamilton to seek a share of the proceeds of the Ven-A-Care settlement, not to seek to unravel the agreement between the parties.³

II. SUN AND HAMILTON CANNOT BRING A RULE 60(b)(6) MOTION BECAUSE NEITHER IS A “PARTY” OR A “LEGAL REPRESENTATIVE” OF A “PARTY” IN THE VEN-A-CARE CASE

Rule 60(b) expressly states that only a “party,” or a “legal representative” of a “party,” may bring a motion under that Rule. This provision has been narrowly construed. “The rule specifically refers to ‘a party or his legal representative.’ We take this to mean that only one who was a party to the original action which gave rise to the final judgment or order now being attacked may be heard to complain of the unfair or incorrect ramifications of that judgment.”

³ Any attempt to attack the underlying settlement on a Rule 60(b)(6) motion is also barred by the express language of 31 U.S.C. § 3730(c)(5), which states, with regard to any “alternate remedy”: “Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.” Thus, because the time for appealing the Ven-A-Care judgment has expired, the settlement is final and cannot be attacked through a Rule 60(b)(6) motion.

Smith v. Missouri Pacific Railroad Co., No. 74565, 1978 WL 101, at *2 (W.D. La. July 31, 1978), *aff'd*, 615 F.2d 683 (5th Cir. 1980). Moreover, if a person seeks to bring a Rule 60(b) motion as a “legal representative” of a party, “only the party’s arguments and claim for relief may be asserted. The representative has no standing to assert his or her own claims and arguments.” *Williams v. Lakin*, No. 06-CV-515-6KF-PJC, 2008 WL 1990473, at *7 (N.D. Okla. May 2, 2008).

In *Western Steel Erection Co. v. United States*, 424 F.2d 737 (10th Cir. 1970), an attorney for a party filed a Rule 60(b) motion, seeking to reopen the judgment after settlement to assert a claim for attorneys’ fees. The Court of Appeals ruled that the attorney could not bring a motion under Rule 60(b) because – although he represented a party in the case as an attorney – he nevertheless was neither a “party” nor a “legal representative” of a “party” within the meaning of the rule. The court held that, because he was pursuing his own interest in seeking to obtain fees, he could not use his status as a legal representative of a party as a basis for standing under Rule 60(b), and therefore he had no standing to bring a motion pursuant to that Rule.

In the Ven-A-Care Case, the United States is a party; Sun and Hamilton are not. The legal interests of the United States have been represented in the Ven-A-Care Case by the Department of Justice, which entered into the settlement and consented to it. Sun and Hamilton are not the “legal representatives” of the United States in the Ven-A-Care Case within the meaning of Rule 60(b) because they are seeking to assert their own claims and arguments. Thus, Sun and Hamilton do not have standing to bring a motion under Rule 60(b)(6).

III. SUN AND HAMILTON CANNOT MEET THE EXACTING STANDARD TO VACATE THE JUDGMENT UNDER RULE 60(b)(6)

Should Sun and Hamilton seek to overturn the complex settlement reached in the Ven-A-Care case, they come nowhere close to meeting the high burden under Rule 60(b)(6) to disrupt a final judgment – particularly one based on a settlement between sophisticated and

experienced parties. “A party seeking relief under Rule 60(b)(6) must demonstrate ‘exceptional circumstances justifying extraordinary relief.’” *Ahmed v. Rosenblatt*, 118 F.3d 866, 891 (1st Cir. 1997) (citing *Valley Citizens for a Safe Environment v. Aldridge*, 969 F.2d 1315, 1317 (1st Cir. 1992) (Breyer, C.J.)). Sun and Hamilton do not cite any First Circuit law regarding the standard for granting a Rule 60(b)(6) motion, mistakenly relying on a Second Circuit case, *United States v. Cirami*, 563 F.2d 26, 32 (2d Cir. 1977), for the proposition that Rule 60(b)(6) “is to be liberally applied.” However, the First Circuit has expressly stated that it “has taken a harsher tack” than other Circuits which grant Rule 60(b) motions more “liberally”; in the First Circuit, a person filing a Rule 60(b)(6) motion has the heavy burden of proving “exceptional circumstances” sufficient to overcome the strong judicial interest in finality of judgments. *Davila-Alvarez v. Escuela de Medicina Universidad Central del Caribe*, 257 F.3d 58, 63-64 (1st Cir. 2001).⁴ Moreover, the First Circuit has made clear that relief under Rule 60(b)(6) is only available in circumstances not covered by other provisions of Rule 60(b) – thus, movants “are not entitled to relief under [Rule 60](b)(6) for claims of excusable neglect.” *Id.* at 67. Sun and Hamilton have patently failed to establish the “exceptional circumstances” that would justify vacating the judgment in the Ven-A-Care Case under Rule 60(b)(6).

Courts have been particularly reluctant to vacate judgments when the judgment resulted from a settlement, in light of the important societal interest in settlement of disputes. For example, in *Brown v. County of Genesee*, 872 F.2d 169, 174 (6th Cir. 1989), the plaintiff asked the district court to vacate a consent agreement. The district court granted the plaintiff’s

⁴ Also misplaced is Sun and Hamilton’s reliance on *Klapprott v. United States*, 335 U.S. 601, 614-15 (1949), an early case interpreting Rule 60(b) which stands for the uncontroversial proposition that the then-recent enactment of the rule was not intended “to deny relief except under circumstances sufficient to have authorized relief under the common law writs of *coram nobis* and *audita querela*.” *Klapprott* does not, as Sun and Hamilton suggest, give courts untrammelled discretion to vacate judgments based solely on a desire to “accomplish justice.”

motion, but the Sixth Circuit reversed. It ruled that “only the existence of fraud or mutual mistake can justify reopening an otherwise valid settlement agreement. ‘One who attacks a settlement must bear the burden of showing that the contract he had made is tainted with invalidity, either by fraud practiced upon him or by a mutual mistake under which both parties acted.’” *Id.* (citation omitted). “A unilateral mistake about a particular fact is insufficient to reform a contract otherwise properly entered into.” *Id.* at 175. Here, Sun and Hamilton have not met their burden of demonstrating either fraud or mutual mistake – at most they have claimed that there was a unilateral mistake on the part of the United States, which, even if proved, would be an insufficient basis to vacate the judgment. Notably, and unlike Sun and Hamilton here, the person seeking to overturn the judgment in *Brown v. County of Genesee* was an actual party to the settlement.

Courts have also been especially unreceptive to arguments that non-signatories to settlement agreements whose rights are affected by the settlement can use a Rule 60(b)(6) motion to set aside the judgment and settlement – particularly when they had notice of the settlement and failed to make an objection before the judgment was entered. For example, in *In re American Investors Life Insurance Co. Annuity Marketing and Sales Practices Litigation*, MDL No. 1712, 2011 WL 6046737 (E.D. Pa. Dec. 6, 2011), a class member brought a motion under Rule 60(b)(6) seeking relief from a settlement in a class action because the release to which the parties agreed as part of the class action settlement was held to bar the class member’s claim in another case. The class member was given notice of the proposed settlement but failed to object before a fairness hearing was held and the settlement was approved by the court. She argued that she was entitled to relief because she was misled as to the impact of the settlement, and because she was ill. The court held that these facts did not constitute the type of “extraordinary circumstances” that would justify relief under Rule 60(b)(6), and the motion was denied.

In *In re Four Seasons Securities Laws Litigation*, 59 F.R.D. 667, 679 (W.D. Okla. 1973), the district court was presented with a motion to vacate a judgment and settlement under Rule 60(b), brought by a class member who received notice of the proposed settlement but failed to object before entry of judgment. The district court ruled that the failure to object did not constitute excusable neglect, despite the fact that the class member was under the mistaken belief, encouraged by one of the parties, that the settlement did not encompass the objector's claims. The district court nevertheless granted the motion to vacate under Rule 60(b)(6), *id.* at 683, but the Tenth Circuit reversed, holding that the motion to vacate should have been denied. *In re Four Seasons Securities Law Litigation*, 502 F.2d 834 (10th Cir. 1974). The Court of Appeals ruled that the fact that the class member was given actual notice and failed to timely object was dispositive, and that allowing an attack on the judgment would undermine the societal interests in finality of judgments and settlement of complex litigation. *Id.* at 843-44. "[S]ince appellants had both actual and constructive knowledge of the settlement and since they took no steps to object to the settlement prior to the entry of judgment," they could not challenge the settlement under Rule 60(b)(6). *See also Pigford v. Veneman*, 307 F. Supp. 2d 43 (D.D.C. 2004) (denying motion by class members, made pursuant to Rule 60(b)(6), to vacate stipulation and order, because class members failed to make timely written objections despite actual notice).

Here, it is undisputed that Sun and Hamilton had actual notice of the settlement agreement. Indeed, their counsel read the settlement agreement, and made an inquiry about the agreement that demonstrated counsel's understanding that the agreement could impact Sun and Hamilton's claims; as this Court held, "it would have been quite predictable that Baxter would seek to cut off all future liability to the federal government." Order at 12. Despite such notice, Sun and Hamilton failed to object to the settlement before entry of judgment. Therefore, they

cannot demonstrate the “extraordinary circumstances” that would justify vacating the judgment under Rule 60(b)(6).

The fact that Sun and Hamilton are *qui tam* relators does not alter this outcome. Assuming, arguendo, that they have the same standing to object to the settlement⁵ in the Ven-A-Care Case as if they were relators in the Ven-A-Care Case, their failure to make a timely objection is fatal to their claim. A relator’s rights in a *qui tam* action are limited by the terms of the FCA. For example, it has been held that the government has the unilateral power to dismiss a *qui tam* action, without intervening in the action, and the court must grant dismissal even if the government’s decision is unreasonable. *United States ex rel. Pentagen Technologies Int’l Ltd. v. United States*, No. 00 CIV. 6167 (DAB), 2001 WL 770940, at *7 (S.D.N.Y. July 10, 2001). Moreover, the court can grant the government’s motion to dismiss a *qui tam* action without a hearing. *Id.*; see also *United States ex rel. Wickliffe v. EMC Corp.*, No. 1:06CV64 DAK, 2010 WL 3662467, at *2 (D. Utah Sept. 15, 2010) (noting that “there is no automatic right to an evidentiary hearing” regarding dismissal of a *qui tam* suit on the government’s motion). While the statute “authorize[s] relators to formally object to any motions to dismiss or proposed settlements between the government and defendant,” a relator does not have an automatic right to a hearing, but must formally object and make a showing of substantial and particularized need for a hearing. *Ridenour v. Kaiser-Hill Co., L.L.C.*, 397 F.3d 925, 931 & n.10 (10th Cir. 2005). This is confirmed by the statute’s legislative history:

Any objections filed by the *qui tam* plaintiff may be accompanied by a petition for an evidentiary hearing on those objections. The Committee does not, intend, however, that evidentiary hearings be granted as a matter of right. We recognize that an automatic right could provoke unnecessary

⁵ Should the court nonetheless grant Sun’s/Hamilton’s Rule 60(b)(6) motion, the court should determine at the outset whether the Advate claim is foreclosed as a matter of law for the independent reasons set forth in our summary judgment papers in the Sun/Hamilton case.

litigation delays. Rather, evidentiary hearings should be granted when the *qui tam* relator shows a ‘substantial need’ for a hearing.

Senate Judiciary Committee, False Claims Amendments Act of 1986, S. Rep. No.

345, 99th Cong., 2d Sess. 26 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5291.

Thus, even if they had the same standing as relators in the Ven-A-Care Case, Sun and Hamilton were required to make a timely objection to the settlement, and make a showing of “substantial need” – which they did not do. That Sun and Hamilton have decided to object now, after entry of judgment, does not constitute the “extraordinary circumstances” that would justify vacating a judgment under Rule 60(b)(6).

IV. SUN AND HAMILTON ARE NOT ENTITLED TO ANY RELIEF BECAUSE THEIR CLAIM IS BARRED BY THE FIRST-TO-FILE RULE

Sun and Hamilton cannot show the “extraordinary circumstances” necessary to vacate the judgment because their claim is barred by the first-to-file rule,⁶ and therefore vacating the judgment in order to allow them to assert such a claim would be futile. *See United States ex rel. MacGregor v. Regents of the University of California*, No. C-99-4148, 2001 WL 674249 (N.D. Cal. May 16, 2001) (motion by *qui tam* relator seeking share of settlement reached in separate proceeding between United States and defendant denied because relator had no right to bring *qui tam* action against defendant in the first place); *see also Ahmed v. Rosenblatt*, 118 F.3d at 891 (“a 60(b)(6) movant must make a suitable showing that the movant has a meritorious claim”).

⁶ Although the first-to-file bar could be the subject of a motion to dismiss in the Sun/Hamilton Case, because judgment has already been entered in the Sun/Hamilton Case, and Sun and Hamilton’s motion for reconsideration in that case has been denied, a motion to dismiss in that case would be pointless, and the appropriate forum in which to raise the first-to-file bar is therefore in opposition to Sun and Hamilton’s Rule 60(b)(6) motion here.

The FCA provides that “[w]hen a person brings an action under this subsection, no person other than the government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. §3730(b)(5). This “first-to-file” rule bars relators “from bringing related actions based on the same underlying facts.” *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001). The rule is consistent with the policy choices embodied in the *qui tam* provisions of the FCA, because “duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.” *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998).

The first-to-file bar is “not limited to situations in which the original and subsequent complaints rely on identical facts.” *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004). In *United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13 (1st Cir. 2009), the First Circuit followed the trend of other circuits and held that the first-to-file rule bars “‘a later allegation [if it] states all the essential facts of a previously-filed claim’ or ‘the same elements of a fraud described in an earlier suit.’” *Id.* at 32 (quoting *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-33 (3d Cir.1998)). Courts applying this rule have taken an expansive view of what constitutes the same “essential facts” or same “elements,” emphasizing, for example, that the complaints must be compared “at a sufficiently high level of generality.” *United States ex rel. Folliard v. CDW Tech. Serv. Inc.*, 722 F. Supp. 2d 37, 41 (D.D.C. 2010). If the first complaint “adequately alleges a broad scheme,” and the second complaint alleges “the same type of wrongdoing as the first,” the second suit is barred by the first-to-file rule, even if the particulars – including the time period

and location – are different. *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 (D.D.C. 2003).

In the recent case of *United States ex rel. Sandager v. Dell Marketing, L.P.*, No. 08-4805 (PAM/TNL), 2012 WL 1453610, at *5-6 (D. Minn. Apr. 26, 2012), the court was called upon to determine whether a first-filed complaint, which alleged the same general fraudulent scheme as the second complaint, but identified different products as the subject of the scheme, barred the second suit. The relator argued that, because the suits alleged that false claims were filed with respect to different products, the first-to-file rule did not bar the second suit, relying for this proposition – as do Sun and Hamilton here – upon this Court’s decision in *In re Pharm. Indus. Average Wholesale Price Litig. (United States ex rel. Ven-A-Care v. Abbott Labs, Inc.)*, MDL No. 1456, 2008 WL 2778808 (D. Mass. July 15, 2008). The *Sandager* court held that *In re Pharm.* did not support the relator’s position, because this Court’s decision did not turn on the fact that the two suits involved “different products” but “on the fact that the drugs were marketed by different divisions within the defendant corporation and involved a different scheme.” *United States ex rel. Sandager*, 2012 WL 1453610, at *5 (emphasis added). Thus, the court concluded, “[t]he *Pharm.* case does not counsel the Court to find the distinctions in products dispositive.” *Id.* at *6. Instead, the court looked to “whether the Government has sufficient notice of the fraudulent scheme through the first-filed complaint.” *Id.* Concluding that “the Government’s investigation of the allegations” in the first complaint “would have revealed the facts underlying the fraudulent scheme” alleged in the second complaint, it held that the first-to-file rule barred the second complaint. *Id.* So long as the fraudulent scheme “is in material respects the same” in both suits, the fact that different products are involved is “immaterial” for purposes of the first-to-file bar. *Id.*

Here, it is clear that the complaint in the Ven-A-Care adequately alleged a broad scheme which encompassed the same wrongdoing as the subsequent Sun/Hamilton complaint. The Ven-A-Care complaint was not narrowly limited to specific products, but cited a few products as examples of the broad scheme alleged. Both the Ven-A-Care and Sun/Hamilton complaints allege the “same elements”: that Baxter knowingly submitting inflated pricing information to drug pricing compendia, thereby causing Medicare, Medicaid, and other payors to pay falsely inflated reimbursement amounts. Ven-A-Care Complaint ¶¶ 1-5, 177-78; Sun/Hamilton Complaint ¶¶ 2, 5, 32-35. Both complaints contain the same “essential facts”: that Baxter marketed the spread to increase profitability (Ven-A-Care Complaint ¶¶ 3, 9, 14, 177; Sun/Hamilton Complaint ¶¶ 5, 6, 32, 34, 36); that it knowingly reported falsely inflated average wholesale prices (“AWPs”) and wholesale acquisition costs (“WACs”) to pricing publications (Ven-A-Care Complaint ¶¶ 74, 178; Sun/Hamilton Complaint ¶¶ 2, 4, 6, 31, 32, 36, 38, 39); that it did so to pricing publications, specifically including First DataBank (Ven-A-Care Complaint ¶¶ 67, 178; Sun/Hamilton Complaint ¶¶ 1, 31, 35, 38); and that it knew Medicare, Medicaid, and other payors would use the falsely inflated published pricing information provided by Baxter to determine reimbursement (Ven-A-Care Complaint ¶¶ 3, 4, 12, 177; Sun/Hamilton Complaint ¶¶ 25, 26, 32, 36). In sum, the alleged fraudulent scheme is, in all material respects, the same in both suits. The Ven-A-Care complaint thus served its purpose of giving the government “enough information to discover related frauds.” Therefore, the fact that the Ven-A-Care suit does not identify Advate by name is immaterial.

The conclusion that the Ven-A-Care complaint bars Sun and Hamilton’s claim is also bolstered by the fact that Advate falls under the same J Code as Recombinate, a hemophilia therapy specifically identified in the Ven-A-Care complaint. Advate is so closely related to

Recombinate that it was included within the same Healthcare Common Procedure Coding System code (J7192) as Recombinate and similar anti-hemophiliac products. *See Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111 (D.D.C. 2009). In assessing whether Baxter participated in the AWP scheme alleged in the Ven-A-Care complaint – and certainly to determine (a) whether Baxter’s published AWPs were above or below the median and (b) the extent to which a “spread” existed at all – the government necessarily had to evaluate all products within J Code 7192, which included Advate. And as we previously demonstrated, Baxter itself informed the government of Advate privacy and AWPs in 2003. *See* fn. 1, *supra*. It is clear that the broad scheme alleged in the Ven-A-Care complaint gave the government enough information to investigate whether the alleged scheme encompassed Advate, thus serving the purposes of the first-to-file bar.

The recent decision in *United States ex rel. Banignan v. Organon USA Inc.*, No. 07-12153-RWZ, 2012 WL 1997874 (D. Mass. June 1, 2012), provides further support for the proposition that the Ven-A-Care complaint, containing allegations of a broad scheme encompassing all of Baxter’s drugs, bars Sun and Hamilton’s later complaint alleging the same scheme and identifying Advate by name. In *Banignan*, one of the defendants, Organon, argued that an earlier complaint in the *Amerisource* case, which alleged a broad scheme in which several pharmaceutical manufacturers allegedly received kickbacks in exchange for increased market share, barred the relator’s suit under the first-to-file rule. The *Amerisource* relator did not identify Organon in its complaint as one of the companies allegedly involved in the kickbacks, and named one of Organon’s products in its original complaint but removed the reference from the body of its amended complaints, relegating the product to a list of “preferred drugs” attached to the complaint. Nevertheless, the court ruled that because the “essential elements of fraud” set

forth in the broad *Amerisource* complaint – “receipt and/or solicitation of kickbacks in exchange for switching patients to ‘preferred’ drugs and filing false or fraudulent Medicaid reimbursement claims for those drugs” – were “sufficient to put the government on the trail of the alleged fraud” that was the subject of the second complaint, the first-to-file rule barred the subsequent complaint against Organon. *Id.* at *7. By contrast, the court rejected a first-to-file argument made by a different defendant, Omnicare, based on different first-filed complaints which had alleged different “specific pharmaceutical manufacturers and drugs” – these “specific” allegations made “the drug itself an essential element of the fraudulent scheme.” *Id.* at *9. In so holding, the court relied on cases such as *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 380 (5th Cir. 2009), which the court characterized as distinguishing between the broad first-to-file bar that applied to first-filed complaints alleging an “industry-wide fraud” and the narrower bar that applied to a complaint which “implicated only four specific insurers among the approximately 95 who participated in the government program at issue.” *Id.* at *9. The court reasoned that the first-to-file issue turned on whether the first-filed complaint provided notice sufficient to allow the government to uncover related frauds without “exhausting its investigative resources.” With respect to defendant Omnicare, the court found that this standard was not met – in contrast to defendant Organon, where the broad *Amerisource* complaint was held to bar the subsequent complaint. Here, the Ven-A-Care complaint, like the *Amerisource* complaint relied on by Organon (but unlike the complaints relied on by Omnicare) is the sort of broad complaint that would “put the government on the trail” of the Sun/Hamilton allegations, without the government “exhausting its resources.” Therefore, under the reasoning of *Banignan*, the Sun/Hamilton complaint is barred by the first-to-file rule.

Because the Sun/Hamilton claim is barred by the first-to-file rule, vacating the judgment to allow Sun/Hamilton to assert their claim would be futile. Thus, the Rule 60(b)(6) motion should be denied for this reason as well.

CONCLUSION

For the foregoing reasons, this Court should deny the Motion of Linnette Sun and Greg Hamilton to Reopen Judgment and for a Hearing.

DATED this 5th day of October 2012.

Respectfully submitted,

/s/ J. Andrew Jackson

J. Andrew Jackson

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